

Certificate of Analysis

Productname: Dihydroergotamini mesilas
Number of analysis/Inspection Code: 3 / KEUR-197452B
Batchnumber: 22A11-F01-384534
Reference code / No.: 1201 / 72121000321
Analysed according to: PH.EUR10.6

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colorless crystals	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification C	Conform	Conform		TLC
Appearance of solution	Clear / <=Y7 or BY7	Conform		
pH	4,4 - 5,4	5,1		0.1%m/V
Specific optical rotation	-47 - -42	-45		1%m/V anhydr. pyridine; dried
Related substances	Conform	Conform		HPLC
Impurity B	<=0,5	0,2	%	
Impurity E	<=0,5	<0,05	%	
Impurity C	<=0,3	0,1	%	
Impurity A	<=0,15	<0,05	%	
Impurity D	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=1,0	0,3	%	
Loss on drying	<=4,0	0,7	%	5 h 105 °C; vacuum
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Dihydroergotamine mesilate	98,0 - 101,0	99,6	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

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Analysis performed by the authorized laboratory Proxylabs.

Manufacturer / Country : Teva Czech Indr.SRO (v/h Ivax) / CZ
CEP :

Release:
Anthony Amoureux
Qualified Person

04/20/23

Expiration: 30-06-26

Conclusion: APPROVED

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